EXHIBIT 4

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELIZABETH DUFFY, JOSEPH CACACCIO, CECIL BYRD, ANTOINETTE SIMS, LAWRENCE EDWARDS, ESTATE OF ELENORA DEUTENBERG, LINDA CROCKER, JENNIFER JOHNSON, MARLIN ANDERSON, and JAMES LAWSON, on behalf of themselves and all others similarly situated, Plaintiffs, v. AUROBINDO PHARMA USA, INC., CVS HEALTH CO., RITE AID CORPORATION, and THROGGS NECK PHARMACY Defendants.	Civil Action No. 1:19-cv-08591-RBK-JS **FIRST AMENDED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Elizabeth Duffy, Joseph Cacaccio, Cecil Byrd, Antoinette Sims, Lawrence Edwards, the estate of Elenora Deutenberg, Linda Crocker, Jennifer Johnson, Marlin Anderson, and James Lawson ("Plaintiffs") bring this action on behalf of themselves and all others similarly situated against Defendants Aurobindo Pharma USA, Inc. ("Aurobindo"), CVS Health Co. ("CVS"), Rite Aid Corporation ("Rite Aid"), and Throggs Neck Pharmacy (collectively "Defendants"). Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Aurobindo, CVS, Rite Aid, and Throggs Neck Pharmacy's manufacturing, distribution, and sale of valsartan-containing generic prescription medications contaminated with N-nitrosodiethylamine ("NDEA"), a carcinogenic

and liver-damaging impurity.

2. Originally marketed under the brand name Diovan, valsartan is a prescription medication mainly used for the treatment of high blood pressure and congestive heart failure. However, due to manufacturing defects originating from Defendants' overseas laboratories in India, eighty lots of Defendants' valsartan-containing products have been recalled because they have been found to contain NDEA.

3. NDEA is classified as a probable human carcinogen. Animal studies have revealed the carcinogenic nature of the compound.

4. On July 13, 2018, the U.S. Food & Drug Administration ("FDA") announced a voluntary recall of several brands of valsartan-containing generic medications. The recall traced back to a Chinese company, Zhejiang Huahai Pharmaceuticals, which supplied the active pharmaceutical ingredient, valsartan, to American subsidiaries, as well as other companies. The recall was due to the presence of N-nitrosodimethylamine ("NDMA") in the recalled valsartan products. The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured."

5. Originally, the recall was thought to have been limited to manufacturing practices in China; however, over the next several months, recalls continued to expand to other overseas laboratories in India.

6. The widespread recalls caused the FDA to evaluate and test additional valsartan-containing medications, which led to the FDA finding an additional impurity, NDEA, in several of the recalled medications.

7. Despite the fact that the first wave of recalls occurred in July of 2018, and the second wave of recalls, implicating manufacturers in India, occurred approximately a month thereafter, Aurobindo did not issue a recall.

8. In fact, Plaintiffs Duffy and Cacaccio, and other class members, were actually switched to Aurobindo's generic valsartan from another contaminated brand because it was represented by Defendants to be safe, and not contaminated. Unfortunately, that was a lie.

9. On December 31, 2018, Aurobindo announced a voluntary nationwide recall of eighty (80) lots of its valsartan-containing medications. Plaintiffs were prescribed, purchased, and used valsartan medication from one of the contaminated lots.

10. The eighty lots of contaminated valsartan-containing medications manufactured and distributed by Defendants are further defined as follows:

NDC	Name and strength	Count	Lot number	Expiry
65862-737-30	Amlodipine and Valsartan Tablets USP5mg/160mg	30	VESA17013-A	10/2019
65862-737-30	Amlodipine and Valsartan Tablets USP5mg/160mg	30	VESA17014-A	10/2019
65862-737-30	Amlodipine and Valsartan Tablets USP5mg/160mg	30	VESA18001-A	12/2019
65862-737-30	Amlodipine and Valsartan Tablets USP5mg/160mg	30	VESA18002-A	12/2019
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA17008-A	10/2019
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA17010-A	10/2019
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA18002-A	01/2020

NDC	Name and strength	Count	Lot number	Expiry
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA18003-A	01/2020
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA18007-A	03/2020
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA18008-A	03/2020
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17008-A	05/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17014-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17015-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17016-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17017-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA18002-A	01/2020
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA18004-A	01/2020
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17012-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17013-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17014-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17015-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17016-A	11/2019

NDC	Name and strength	Count	Lot number	Expiry
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17017-A	11/2019
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA17009-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP 10mg /320mg	30	VKSA18005-A	03/2020
65862-740-30	Amlodipine and Valsartan Tablets USP 10mg /320mg	30	VKSA18001-A	01/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17033-A	10/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17034-A	10/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17035-A	10/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17036-A	10/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17037-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17033-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17034-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17035-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17036-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17040-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17041-A	11/2020

NDC	Name and strength	Count	Lot number	Expiry
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17042-A	11/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17043-A	11/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17049-A	08/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17054-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17055-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17056-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17057-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17058-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17059-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17060-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17062-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17066-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17067-A	11/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17068-A	11/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17069-A	11/2020

NDC	Name and strength	Count	Lot number	Expiry
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18001-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18002-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18003-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18004-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18005-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18006-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18007-A	12/2020
65862-547-90	Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg	90	HVSA17011-A	11/2020
65862-547-90	Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg	90	HVSA17012-A	11/2020
65862-547-90	Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg	90	HVSA18001-A	12/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17023-A	08/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17036-A	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17037-A	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17038-A	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17039-A	11/2020

NDC	Name and strength	Count	Lot number	Expiry
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17040-B	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB18001-A	12/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB18002-A	12/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB18003-A	12/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB18004-A	12/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP 160mg/12.5mg	90	HTSA17037-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP 160mg/12.5mg	90	HTSA17039-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17063-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17064-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17065-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP & 320/25mg	90	HTSB18029-A	03/2021
65862-573-90	Valsartan Tablets USP 320mg	90	VUSD17008-A	07/2019
65862-573-90	Valsartan Tablets USP 320mg	90	VUSD17009-A	09/2019

11. The FDA announced that the recall was "to the consumer level due to the detection of trace amounts of an unexpected impurity found in the finished drug product. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA), which is a

substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification."

12. At all times during the period alleged herein, Aurobindo represented and warranted to consumers that its generic valsartan-containing drugs ("VCDs") were therapeutically equivalent to and otherwise the same as their respective Reference Listed Drugs ("RLDs"), namely, DIOVAN, DIOVAN HCT, EXFORGE, and EXFORGE HCT, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

Aurobindo failed to promptly recall its valsartan medications, despite the fact that Aurobindo sourced valsartan from overseas labs in India, which were implicated in prior recalls.

13. After several waves of recalls, on January 2, 2019, Aurobindo issued a voluntary recall of eighty (80) lots of its valsartan-containing medications.

14. Previous recalls, such as the Camber Pharmaceuticals recall announced on August 8, 2018 and the Mylan Pharmaceuticals recall announced on November 20, 2018, implicated manufacturing facilities in India as a source of contaminated valsartan medication.

15. Aurobindo failed to promptly recall its valsartan-containing medications for over five months after the initial recall was announced, and over four months after labs in India were implicated. Aurobindo failed to do so despite knowing that its valsartan-containing medication was also contaminated.

16. Aurobindo reaped a substantial windfall from this non-disclosure, as patients like Plaintiffs Duffy and Cacaccio, and other class members, were actually switched to Aurobindo's valsartan-containing medications from previously-recalled brands.

17. All the while, Aurobindo was manufacturing and distributing valsartan-containing medication contaminated with NDEA.

18. Like NDMA, NDEA is acutely toxic when consumed orally.

Aurobindo boasts about the quality and safety of its valsartan products, despite the fact that they are contaminated with NDEA and unfit for human use.

19. Generic drugs reach the market when the brand-name version of the drug comes off patent, and other competitors are able to seek approval for, market, and sell bioequivalent versions of the brand-name drug. These generic equivalents are supposed to be of equal quality and equal safety. According to the FDA, "[a]ll generic drugs approved by [the] FDA have the same high quality, strength, purity, and stability as brand-name drugs."

20. Here, the valsartan-containing drugs manufactured by Aurobindo are supposed to be equivalent to the brand-name drug, Diovan. However, they are not because they suffer from a manufacturing defect which caused certain lots of Defendants' generic valsartan to be contaminated with NDEA.

21. As such, Aurobindo's valsartan-containing medications are neither safe nor of equal quality to the brand-name version of the medication.

22. Not only did Aurobindo's valsartan-containing medications fail to live up to FDA standards, but Aurobindo falsely boasts about the quality and efficacy of its medications on its website, in its packaging, and in other materials presented to the consumer, which were relied upon by Plaintiffs and class members in deciding to purchase their valsartan-containing medication from Defendants.

23. For example, as to Active Pharmaceutical Ingredient ("API") manufacturing, Aurobindo boasts on its website:

> Committed to **quality**, **safety** and the environment, five of our manufacturing facilities have been inspected and approved by the US FDA, UK MHRA, TGA Australia, ANVISA and other trusted regulatory agencies. **Our state-of-the-art manufacturing plants ensure that we deliver quality and scale.** We have successfully integrated our capabilities and capacities to deliver a wide product portfolio that caters to the needs of diverse markets. Aurobindo operates dedicated facilities for categories from intermediates to oral and sterile beta lactams. There are multiple site filings to mitigate the supply risk and to ensure business continuity. Aurobindo API plants are equipped with particle size modifications systems to supply compacted and micronized materials. Manufacturing is backed by warehousing systems that offer ambient control room temperature (CRT) and cold rooms. API plants are equipped by site dedicated quality control laboratories.[1]

24. These warranties by the Aurobindo are false, as its valsartan API is contaminated with carcinogenic NDEA. An internal review should have caught the manufacturing defect that caused its medications to be contaminated with NDEA, but it did not. In fact, it took over five months for Aurobindo to issue a voluntary recall after the initial wave of recalls was announced.

25. The representations made by Aurobindo regarding the quality of its medications was a material misrepresentation that was relied upon by Plaintiffs and Class Members.

26. Aurobindo has had issues with quality control in the past.

27. On April 19, 2017, the FDA issued a Form 483 report following an inspection of one of Aurobindo Pharma Ltd.'s manufacturing facilities. The inspection's observations included that "[l]aboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity."[2] On February 20, 2018, the FDA issued a Form 483 for another Aurobindo Pharma Ltd.

[1] https://www.aurobindo.com/about-us/business-units/api/ (last visited 1/2/2018).
[2] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM556141.pdf

manufacturing facility, observing that "[t]he statistical quality control criterial fail to include appropriate acceptance levels and rejection levels."[3]

28. On October 26, 2018, Aurobindo Parma Ltd. voluntarily recalled twenty-two (22) batches of another drug substance, Irbesartan, due to the presence of NDEA.

Plaintiffs and Class Members were harmed by purchasing and consuming contaminated valsartan-containing medications manufactured, distributed, and sold by Defendants.

29. Plaintiffs and the Class were injured by the full purchase price of their valsartan-containing medications. These medications are worthless, as they are contaminated with carcinogenic and harmful NDEA, and therefore are not fit for human consumption. Indeed, Plaintiffs have been instructed to stop using the medication, and Aurobindo is initiating a program for return of all recalled products. Plaintiffs are further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDEA, and for damages related to Defendants' conduct.

30. Plaintiffs bring this action on behalf of themselves and Class Members for equitable relief and to recover damages and restitution for: (i) breach of express warranty; (ii) breach of the implied warranty of merchantability; (iii) violation of New York's General Business Law § 349; (iv) violation of New York's General Business Law § 350; (v) violation of South Carolina's Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5-10, *et seq*.; (vi) unjust enrichment; (vii) fraudulent concealment; (viii) fraud; (ix) conversion; (x) strict products liability; (xi) gross negligence; (xii) negligence; and (xiii) battery.

PARTIES

31. Plaintiff Elizabeth Duffy is a citizen of New York who resides in the Bronx, New

[3] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM599547.pdf

York. Plaintiff Duffy was prescribed valsartan-containing medication manufactured and distributed by Aurobindo and sold by Defendant Throggs Neck Pharmacy. Plaintiff Duffy was switched to Aurobindo's valsartan after the initial wave of recalls, which was due to Defendants' representations that the medication was safe. Plaintiff Duffy was prescribed one of Aurobindo's recalled valsartan products, bearing the NDC number 65862-551-90. Defendant Throggs Neck Pharmacy failed to notify Plaintiff Duffy of the recall. When purchasing her valsartan-containing medications from Defendants Aurobindo and Throggs Neck Pharmacy, Plaintiff Duffy reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured and free from contaminants and defects. Plaintiff Duffy relied on these representations and warranties in deciding to purchase her valsartan-containing medications from Defendants Aurobindo and Throggs Neck Pharmacy, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased her valsartan-containing medications from Defendants Aurobindo and Throggs Neck Pharmacy if she had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Duffy also understood that in making the sale, Throggs Neck Pharmacy was acting with the knowledge and approval of Aurobindo and/or as the agent of Aurobindo. Plaintiff Duffy also understood that each purchase involved a direct transaction between herself and Aurobindo, because her medication came with packaging and other materials prepared by Aurobindo, including representations and warranties that her medications were properly manufactured and free from contaminants and defects.

32. Plaintiff Joseph Cacaccio is a citizen of New York who resides in Levittown, New York. Plaintiff Cacaccio was prescribed Aurobindo's valsartan-containing medication, which he

purchased from Defendant Rite Aid in Bethpage, New York. Plaintiff Cacaccio was prescribed one of Defendants' recalled valsartan products, bearing the NDC number 65862-551-90. When purchasing his valsartan-containing medications from Defendants Aurobindo and Rite Aid, Plaintiff Cacaccio reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured and free from contaminants and defects. Plaintiff Cacaccio relied on these representations and warranties in deciding to purchase his valsartan-containing medications from Defendants Aurobindo and Rite Aid, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased his valsartan-containing medications from Defendants Aurobindo and Rite Aid if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Cacaccio also understood that in making the sale, Rite Aid was acting with the knowledge and approval of Aurobindo and/or as the agent of Aurobindo. Plaintiff Cacaccio also understood that each purchase involved a direct transaction between himself and Aurobindo because his medication came with packaging and other materials prepared by Aurobindo, including representations and warranties that his medications were properly manufactured and free from contaminants and defects.

33. Plaintiff Cecil Byrd is a citizen of South Carolina who resides in Orangeburg, South Carolina. Plaintiff Byrd was prescribed Aurobindo's valsartan-containing medication, which he purchased from Defendant CVS in Orangeburg, South Carolina. Plaintiff Byrd was prescribed at least one of Defendants' recalled valsartan products, bearing NDC number 65862-548-90. When purchasing his valsartan-containing medications from Defendants Aurobindo and CVS, Plaintiff Byrd reviewed the accompanying labels and disclosures, and understood them as

representations and warranties by both the manufacturer and pharmacy that the medications were properly manufactured and free from contaminants and defects. Plaintiff Byrd relied on these representations and warranties in deciding to purchase his valsartan-containing medications from Defendants Aurobindo and CVS, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased his valsartan-containing medications from Defendants Aurobindo and CVS if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Byrd also understood that in making the sale, CVS was acting with the knowledge and approval of Aurobindo and/or as the agent of Aurobindo. Plaintiff Byrd also understood that each purchase involved a direct transaction between himself and Aurobindo, because his medication came with packaging and other materials prepared by Aurobindo, including representations and warranties that his medications were properly manufactured and free from contaminants and defects.

34. Antoinette Sims is a New Jersey resident and citizen. During the class period, Plaintiff Sims paid money for Aurobindo's VCDs, including VCDs manufactured, distributed, and/or sold by Aurobindo. Aurobindo expressly and impliedly warranted to Plaintiff Sims that their respective generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Sims known the product was not the same as the RLD, Plaintiff Sims would not have paid for Aurobindo's VCDs. Likewise, had Aurobindo's deception about the impurities within their products been made known earlier, Plaintiff Sims would not have paid for Aurobindo's VCDs.

35. Plaintiff Lawrence Edwards is a Georgia resident and citizen. During the class period, Plaintiff Edwards paid money for one or more of Aurobindo's VCDs, including VCDs manufactured, distributed, and/or sold by Aurobindo. Aurobindo expressly and impliedly

warranted to Plaintiff Edwards that its generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Edwards known the product was not the same as the RLD, Plaintiff Edwards would not have paid for Aurobindo's VCDs. Likewise, had Aurobindo's deception about the impurities within their products been made known earlier, Plaintiff Edwards would not have paid for Aurobindo's VCDs.

36. Elenora Deutenberg was a Florida resident and citizen, and her Estate brings this claim. During the class period, Plaintiff Estate of Eleona Deutenberg paid money for Aurobindo's VCDs, including VCDs manufactured, distributed, and/or sold by Aurobindo. Defendants expressly and impliedly warranted to Plaintiff Estate of Elenora Deutenberg that its generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Estate of Eleona Deutenberg known the product was not the same as the RLD, Plaintiff Estate of Eleona Deutenberg would not have paid for Aurobindo's VCDs. Likewise, had Aurobindo's deception about the impurities within their products been made known earlier, Plaintiff Estate of Eleona Deutenberg would not have paid for Aurobindo's VCDs.

37. Plaintiff Linda Crocker is a Maine resident and citizen. During the class period, Plaintiff Crocker paid money for one or more of Aurobindo's VCDs, including VCDs manufactured, distributed, and/or sold by Aurobindo. Aurobindo expressly and impliedly warranted to Plaintiff Crocker that its generic VCD products were the same as its RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Crocker known the product was not the same as the RLD, Plaintiff Crocker would not have paid for Aurobindo's VCDs. Likewise, had Aurobindo's deception about the impurities within their products been

made known earlier, Plaintiff Crocker would not have paid for Aurobindo's VCDs.

38. Jennifer Johnson is a Minnesota resident and citizen. During the class period, Plaintiff Johnson paid money for one or more of Defendants' VCDs, including VCDs manufactured, distributed, and/or sold by Aurobindo. Aurobindo expressly and impliedly warranted to Plaintiff Johnson that its generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Johnson known the product was not the same as the RLD, Plaintiff Johnson would not have paid for Aurobindo's VCDs. Likewise, had Aurobindo's deception about the impurities within their products been made known earlier, Plaintiff Johnson would not have paid for Aurobindo's VCDs.

39. Plaintiff Marlin Anderson is an Illinois resident and citizen. During the class period, Plaintiff Anderson paid money for one or more of Aurobindo's VCDs, including VCDs manufactured, distributed, and/or sold by Aurobindo. Aurobindo expressly and impliedly warranted to Plaintiff Anderson that its generic VCD products were the same as their RLDs. In fact, Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Anderson known the product was not the same as the RLD, Plaintiff Anderson would not have paid for Aurobindo's VCDs. Likewise, had Aurobindo's deception about the impurities within their products been made known earlier, Plaintiff Anderson would not have paid for Aurobindo's VCDs.

40. Plaintiff James Lawson is a New Jersey resident and citizen. During the class period, Plaintiff Lawson paid money for one or more of Aurobindo's VCDs, including VCDs manufactured, distributed, and/or sold by Aurobindo. Aurobindo expressly and impliedly warranted to Plaintiff Lawson that its generic VCD products were the same as its RLDs. In fact,

Plaintiff purchased a product that was not the same as the RLD. Had Plaintiff Lawson known the product was not the same as the RLD, Plaintiff Lawson would not have paid for Defendants' VCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Lawson would not have paid for Defendants' VCDs.

41. Defendant Aurobindo Pharma USA, Inc. is a limited liability company organized under the laws of the State of Delaware and maintains its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520. Defendant Aurobindo Pharma USA, Inc. conducts substantial business in the State of New York, the State of South Carolina, and nationwide. Defendant Aurobindo Pharma USA, Inc. has been engaged in the manufacturing, sale, and distribution of contaminated generic valsartan in the United States, including in New York and South Carolina. Defendant Aurobindo Pharma USA, Inc. is, upon information and belief, the United States subsidiary of Aurobindo Pharma Ltd., which, upon information and belief, manufactures generic drugs and API in laboratories in India.

42. Defendant Throggs Neck Pharmacy is, upon information and belief, a corporation organized under the laws of the State of New York and maintains its principal place of business at 3569 E. Tremont Ave, Bronx, NY 10465. Among other services, Throggs Neck Pharmacy provides pharmacy services. Defendant Throggs Neck Pharmacy conducts substantial business in the State of New York. Plaintiff Duffy purchased her valsartan-containing medication at Throggs Neck Pharmacy in the Bronx, New York.

43. Defendant Rite Aid Corporation is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Defendant Rite Aid Corporation sells Aurobindo's valsartan-containing medication throughout the United States, and specifically in the State of New York. Plaintiff

Joseph Cacaccio purchased his valsartan-containing medication at a Rite Aid location in Bethpage, New York.

44. Defendant CVS Health Co. is, upon information and belief, a corporation organized under the laws of the State of Rhode Island and Providence Plantations and maintains its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. Among other services, CVS provides pharmacy services. Defendant CVS conducts substantial business throughout the United States, and specifically in the state of South Carolina. Plaintiff Byrd purchased his valsartan-containing medication at a CVS location in Orangeburg, South Carolina.

JURISDICTION AND VENUE

45. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below (the "Class"), is a citizen of a different state than Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

46. Venue is proper in the Southern District of New York pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, Plaintiff Duffy resides in this District, and because Defendants (a) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of contaminated valsartan-containing medications in this District; (b) conduct substantial business in this District; and (c) are subject to personal jurisdiction in this District.

47. Venue is proper in this District on account of the MDL consolidation pursuant to 28 U.S.C. § 1407 and because: Defendants reside in this District, 28 U.S.C. § 1391(b)(1);

because "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and because Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

CLASS ALLEGATIONS

48. Plaintiffs seek to represent a class defined as all persons in the United States who purchased or paid for valsartan-containing medications that are contaminated with NDEA (the "Nationwide Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint venturers, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

49. Plaintiffs Duffy and Cacaccio also seek to represent a subclass of all Class members who purchased valsartan-containing medications in New York (the "New York Subclass").

50. Plaintiff Byrd also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in South Carolina (the "South Carolina Subclass").

51. Plaintiffs Sims and Lawson also seek to represent a subclass of all Class members who purchased valsartan-containing medications in New Jersey (the "New Jersey Subclass").

52. Plaintiff Edwards also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Georgia (the "Georgia Subclass").

53. Plaintiff Estate of Elenora Deutenberg also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Florida (the "Florida

Subclass").

54. Plaintiff Linda Crocker also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Maine (the "Maine Subclass").

55. Plaintiff Johnson also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Minnesota (the "Minnesota Subclass").

56. Plaintiff Anderson also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in Illinois (the "Illinois Subclass").

57. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

58. The Nationwide Class and state subclasses are collectively referred to as the "Class."

59. **Numerosity**. The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiffs, the true number of Class members is known by Defendants. More specifically, Defendants maintain databases that contain the following information: (i) the name of each Class member who was prescribed the contaminated medication; (ii) the address of each Class member; and (iii) each Class member's payment information related to the contaminated medication. Thus, Class members may be identified and notified of the pendency of this action by U.S. Mail, electronic mail, and/or published notice, as is customarily done in consumer class actions.

60. **Existence and predominance of common questions of law and fact**. Common

questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the valsartan-containing medications manufactured, distributed, and sold by Defendants were in fact contaminated with NDEA, thereby breaching the express and implied warranties made by Defendants and making the medication unfit for human consumption and therefore unfit for their intended purpose, and constituting a clear manufacturing defect for purposes of strict liability and negligence, as well as battery as to the victims of the contaminated medication;

(b) whether Defendants knew or should have known that the valsartan-containing medications were in fact contaminated with NDEA prior to the recall, thereby constituting fraud and/or fraudulent concealment, and negligence or gross negligence, and negligence per se;

(c) whether Defendants have unlawfully converted money from Plaintiffs and the Class;

(d) whether Defendants are liable to Plaintiffs and the Class for unjust enrichment;

(e) whether Defendants are liable to Plaintiffs and the Class for fraudulent concealment;

(f) whether Defendants are liable to Plaintiffs Duffy and Cacaccio, and the Class, for violation of the New York General Business Law §§ 349 & 350, *et seq.*;

(g) whether Defendants are liable to Plaintiff Byrd and the Class for violation of the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5-10, *et seq.*;

(h) whether Defendants are liable to Plaintiffs for breaches of express and implied warranty;

(i) whether Plaintiffs and the Class have sustained monetary loss and the proper measure of that loss;

(j) whether Plaintiffs and Class are entitled to declaratory and injunctive relief;

(k) whether Plaintiffs and the Class are entitled to restitution and disgorgement from Defendants; and

(l) Whether the marketing, advertising, packaging, labeling, and other promotional materials for the products are deceptive.

61. **Typicality.** Plaintiffs' claims are typical of the claims of the other members of the Class in that Defendants mass marketed and sold contaminated medications to consumers throughout the United States. This contamination was present in all of the recalled medications manufactured, distributed, and sold by Defendants. Therefore, Defendants breached their express and implied warranties to Plaintiffs and Class members by manufacturing, distributing, and selling the contaminated valsartan medication. Plaintiffs' claims are typical in that they were uniformly harmed in purchasing and consuming the contaminated medications. Plaintiffs' claims are further typical in that Defendants deceived Plaintiffs in the very same manner as they deceived each member of the Class. Further, there are no defenses available to Defendants that are unique to Plaintiffs.

62. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on behalf of the Class. Furthermore, Plaintiffs have no interests that are antagonistic to those of the Class.

63. **Superiority.** A class action is superior to all other available means for the fair

and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

64. In the alternative, the Class may also be certified because:

(a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudication with respect to individual Class members that would establish incompatible standards of conduct for the Defendants;

(b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendants have acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

COUNT I
Breach Of Express Warranty

(On Behalf Of The Nationwide Class)

65. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

66. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

67. Plaintiffs, and each member of the nationwide Class, formed a contract with Defendants at the time Plaintiffs and the other Class members purchased the contaminated valsartan medications. The terms of the contract include the promises and affirmations of fact made by Defendants on the contaminated medication's packaging and through marketing and advertising, including that the product would be of "quality" and "safe." This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendants.

68. Defendants further expressly warranted that the valsartan-containing medications would contain only what was stated on the label, and would not contain harmful and carcinogenic defects and impurities such as NDEA. Plaintiffs relied on the express warranty that their medication would contain only what was stated on the label, and that it would not be contaminated with impurities. These express warranties further formed the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendants.

69. Defendants purport, through their advertising, labeling, marketing, and packaging to create an express warranty that the medication would be of the same "quality" and the "bioequivalent" of the name-brand medication, and that it would be "safe."

70. Plaintiffs and the Class performed all conditions precedent to Defendants' liability under this contract when they purchased the contaminated medication.

71. Defendants breached express warranties about the contaminated medication and their qualities because Defendants' statements about the contaminated medications were false and the contaminated medication does not conform to Defendants' affirmations and promises described above.

72. Plaintiffs and each of the members of the Class would not have purchased the contaminated medication had they known the true nature of the contaminated medication's ingredients and what the contaminated medication contained (*i.e.*, NDEA).

73. As a result of Defendants' breaches of express warranty, Plaintiffs and each of the members of the Class have been damaged in the amount of the purchase price of the subject valsartan medications and any consequential damages resulting from the purchases.

74. On January 3, 2019, prior to filing this action, Defendants were served with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiffs' counsel sent Defendants a letter advising them that they breached an express warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiffs' counsel's letter is attached hereto as Exhibit A.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Nationwide Class)

75. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

76. Plaintiffs bring this claim individually and on behalf of the members of the

proposed Class, New York Subclass, and the South Carolina Subclass against Defendants.

77. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that the valsartan-containing medications (i) contained no NDEA and (ii) are generally recognized as safe for human consumption.

78. Defendants breached the warranty implied in the contract for the sale of the contaminated valsartan-containing medications because they could not pass without objection in the trade under the contract description, the goods were not of fair average quality within the description, and the goods were unfit for their intended and ordinary purpose because the valsartan-containing medications manufactured, distributed, and sold by Defendants were contaminated with carcinogenic and liver toxic NDEA, and as such are not generally recognized as safe for human consumption. As a result, Plaintiffs and Class members did not receive the goods as impliedly warranted by Defendants to be merchantable.

79. Plaintiffs and Class members purchased the valsartan-containing medications in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

80. The valsartan-containing medications were not altered by Plaintiffs or Class members.

81. The valsartan-containing medications were defective when they left the exclusive control of Defendants.

82. Defendants knew that the valsartan-containing medications would be purchased and used without additional testing by Plaintiffs and Class members.

83. The contaminated valsartan medication was defectively manufactured and unfit for its intended purpose, and Plaintiffs and Class members did not receive the goods as

warranted.

84. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiffs and Class members have been injured and harmed because: (a) they would not have purchased the valsartan-containing medication on the same terms if they knew that the products contained NDEA, and are not generally recognized as safe for human consumption; and (b) the valsartan-containing medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT III
Violation Of New York's General Business Law § 349
(On Behalf Of The New York Subclass)

85. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

86. Plaintiffs Duffy and Cacaccio bring this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

87. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

88. In its sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of New York's General Business Law § 349.

89. Plaintiffs Duffy and Cacaccio, and members of the Subclass, are consumers who purchased products from Defendants for their personal use.

90. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the valsartan-containing medications (i) contained no NDEA or other harmful impurities; and (ii)

are generally recognized as safe for human consumption.

91. The foregoing deceptive acts and practices were directed at consumers.

92. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the valsartan-containing medications manufactured, distributed, and sold by Defendants to induce consumers to purchase the same.

93. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

94. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiffs Duffy and Cacaccio and members of the Subclass have sustained from having paid for and consumed Defendants' products.

95. As a result of Defendants' violations, Plaintiffs Duffy and Cacaccio and members of the Subclass have suffered damages because: (a) they would not have purchased Defendants' valsartan-containing medications on the same terms if they knew that the products contained NDEA, and are not generally recognized as safe for human consumption; and (b) Defendants' valsartan products do not have the characteristics, ingredients, uses, or benefits promised.

96. On behalf of themselves and other members of the Subclass, Plaintiffs Duffy and Cacaccio seek to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Violation Of New York's General Business Law § 350
(On Behalf Of The New York Subclass)

97. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

98. Plaintiffs Duffy and Cacaccio bring this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

99. Based on the foregoing, Defendants engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York GBL.

100. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to, that the medication was safe and was not tainted with harmful impurities such as NDEA ("the Misrepresentations"), were and are directed to consumers.

101. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

102. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, have resulted in consumer injury or harm to the public interest.

103. Plaintiffs Duffy and Cacaccio and members of the New York Subclass have been injured because: (a) they would not have purchased the contaminated valsartan-containing medication if they had known that the medications contained liver-toxic and carcinogenic NDEA; and (b) the medications do not have the characteristics, uses, or benefits as promised, namely that the medications were contaminated with NDEA. As a result, Plaintiffs Duffy and Cacaccio and members of the New York Subclass have been damaged in the full amount of the purchase price of the medications.

104. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, Plaintiffs Duffy and

Cacaccio have suffered and will continue to suffer economic injury.

105. Plaintiffs Duffy and Cacaccio and members of the New York Subclass suffered an ascertainable loss caused by Defendants' Misrepresentations because they paid more for the medications than they would have had they known the truth about the Products (*i.e.*, the full purchase price).

106. On behalf of themselves and other members of the New York Subclass, Plaintiffs Duffy and Cacaccio seek to enjoin the unlawful acts and practices described herein, to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
Violation Of South Carolina's Unfair Trade Practices Act,
S.C. Code Ann. §§ 39-5-10, *et seq*.
(On Behalf Of The South Carolina Class)

107. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

108. Plaintiff Byrd brings this claim individually and on behalf of the members of the proposed South Carolina Subclass.

109. The South Carolina Unfair Trade Practices Act § 39-5-20(a) prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce . . . ."

110. In its sale of goods throughout the state of South Carolina, Defendants conduct business and trade within the meaning and intendment of South Carolina's Unfair Trade Practices Act.

111. Plaintiff Byrd and members of the South Carolina Subclass are consumers who purchased products from Defendants for their personal use.

112. By the acts and conduct alleged herein, Defendants have engaged in deceptive,

unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the valsartan-containing medications (i) contained no NDEA or other harmful impurities; and (ii) are generally recognized as safe for human consumption.

113. The foregoing deceptive acts and practices were directed at consumers.

114. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the valsartan-containing medications manufactured, distributed, and sold by Defendants to induce consumers to purchase the same.

115. By reason of this conduct, Defendants engaged in deceptive conduct in violation of South Carolina's Unfair Trade Practices Act.

116. As a result of Defendants' violations, Plaintiff Byrd and members of the South Carolina Subclass have suffered damages because: (a) they would not have purchased Defendants' valsartan-containing medications on the same terms if they knew that the products contained NDEA, and are not generally recognized as safe for human consumption; and (b) Defendants' valsartan products do not have the characteristics, ingredients, uses, or benefits promised.

117. On behalf of himself and other members of the South Carolina Subclass, Plaintiff and the South Carolina Subclass seek to recover their actual damages, three times actual damages, and reasonable costs and attorneys' fees.

118. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VI
Unjust Enrichment
(On Behalf Of The Nationwide Class)

119. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

120. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

121. Plaintiffs and the Class conferred a benefit on Defendants in the form of monies paid to purchase Defendants' contaminated valsartan medication.

122. Defendants voluntarily accepted and retained this benefit.

123. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for contaminated medications unfit for human use, it would be unjust and inequitable for the Defendants to retain it without paying the value thereof.

COUNT VII
Fraudulent Concealment
(On Behalf Of The Nationwide Class)

124. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

125. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

126. Defendants had a duty to disclose material facts to Plaintiffs and the Class given their relationship as contracting parties and intended users of the medication. Defendants also had a duty to disclose material facts to Plaintiffs and the Class, namely that they were in fact manufacturing, distributing, and selling harmful and contaminated medications unfit for human consumption, because Defendants had superior knowledge such that the transactions without the

disclosure were rendered inherently unfair.

127. Defendants possessed knowledge of these material facts. In fact, Defendants failed to announce a recall for over five months after the initial recall was announced. Further, reports from government agencies reveal that this contamination may date back to 2012. Defendants therefore withheld the knowledge of the contamination for nearly six years before finally disclosing the issue. During that time, Plaintiffs and Class members were using the medication without knowing it contained the harmful impurity NDEA. In fact, Plaintiffs Duffy and Cacaccio were switched to the Aurobindo's valsartan medication from another recalled brand, under the mistaken belief that it was safe for human use, when in fact it was not.

128. Defendants failed to discharge their duty to disclose these materials facts.

129. In so failing to disclose these material facts to Plaintiffs and the Class, Defendants intended to hide from Plaintiffs and the Class that they were purchasing and consuming medications with harmful impurities that were unfit for human use, and thus acted with scienter and/or an intent to defraud. As discussed above, Defendants obtained a substantial financial benefit as a result of their fraudulent concealment of the contaminated nature of the medication.

130. Plaintiffs and the Class reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the contaminated valsartan medication manufactured, distributed, and sold by Defendants had they known it was contaminated with NDEA.

131. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiffs and the Class suffered damages in the amount of monies paid for the defective medication.

132. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VIII
Fraud
(On Behalf Of The Nationwide Class)

133. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

134. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

135. As discussed above, Defendants provided Plaintiffs and Class members with false or misleading material information about the valsartan medications manufactured, distributed, and sold by Defendants, including but not limited to Aurobindo's statement that:

> Committed to **quality**, **safety** and the environment, five of our manufacturing facilities have been inspected and approved by the US FDA, UK MHRA, TGA Australia, ANVISA and other trusted regulatory agencies. **Our state-of-the-art manufacturing plants ensure that we deliver quality and scale.** We have successfully integrated our capabilities and capacities to deliver a wide product portfolio that caters to the needs of diverse markets. Aurobindo operates dedicated facilities for categories from intermediates to oral and sterile beta lactams. There are multiple site filings to mitigate the supply risk and to ensure business continuity. Aurobindo API plants are equipped with particle size modifications systems to supply compacted and micronized materials. Manufacturing is backed by warehousing systems that offer ambient control room temperature (CRT) and cold rooms. API plants are equipped by site dedicated quality control laboratories.

136. As indicated above, however, these representations are false as its valsartan medications were contaminated with carcinogenic NDEA.

137. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiffs and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiffs and Class members to purchase these contaminated valsartan-containing medications.

138. Defendants knew that the medications contained these harmful impurities, but continued to manufacture them, even after other manufacturers from India voluntarily recalled their products. In fact, reports from government agencies reveal that this contamination can date back to 2012. During that time that Defendants knew of but failed to disclose the contamination, Plaintiffs and Class Members were using the medication without knowing it contained the harmful impurity NDEA.

139. The fraudulent actions of Defendants caused damage to Plaintiffs and Class members, who are entitled to damages and other legal and equitable relief as a result.

140. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT IX
Conversion
(On Behalf Of The Nationwide Class)

141. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

142. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

143. Plaintiffs and the Class have an ownership right to the monies paid for the contaminated medication manufactured, distributed, and sold by Defendants.

144. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the contaminated medication. Defendants have done so every time that Plaintiffs and the Class have paid to have their prescriptions filled.

145. As a direct and proximate cause of Defendants' conversion, Plaintiffs and the Class suffered damages in the amount of the payments made for each time they filled their

prescriptions.

COUNT X
Strict Liability – Manufacturing Defect
(On Behalf Of The Nationwide Class)

146. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

147. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

148. The NDEA impurity contained in the Defendants' medications was a mishap in the manufacturing process which led to the valsartan medications containing the harmful impurity NDEA. NDEA was not intended to be included in the medication; it was an impurity that was created due to an error in the manufacturing process.

149. Due to the NDEA impurity, the product was not reasonably safe as marketed because NDEA is a known carcinogen and is damaging to the liver, and, according to the FDA, the level of NDEA in the effected medication far exceeded acceptable levels, warranting an immediate recall of the effected medication.

150. NDEA is acutely toxic and therefore immediately causes injury when ingested.

151. Plaintiffs and all Class members used the product for its intended purpose, meaning they used the product as prescribed by their respective doctors.

152. There is no way that Plaintiffs or Class members could have discovered the defect by exercising reasonable care. There was no way for Plaintiffs or Class Members to tell by visually observing, tasting, or smelling the medication that it was in fact contaminated with NDEA. Nothing short of laboratory tests (which should have been done by Defendants for quality control purposes) would have revealed the defect to the unsuspecting consumer.

153. Because Plaintiffs and Class members had no way of knowing that their medication was in fact contaminated, Plaintiffs and Class members could not have avoided the injury by exercising ordinary care.

154. Defendants were supposed to manufacture, distribute, and sell valsartan-containing medications without any harmful impurities such as NDEA. The valsartan medications were not designed or intended to contain NDEA. The impurity resulted from a manufacturing defect which allowed the medication to become contaminated.

155. Plaintiffs and Class Members suffered harm as a result of consuming this contaminated medication. The ingestion of NDEA is acutely harmful. NDEA, when ingested orally, is immediately harmful to the liver, kidneys, and pulmonary function. "Acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours." As such, NDEA causes harm as soon as it is consumed.

156. Importantly, Plaintiffs and the Class members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiffs and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

157. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a manufacturing defect which caused Plaintiffs and Class Members an immediate and concrete harm, Defendants are strictly liable to Plaintiffs and Class Members.

COUNT XI
Gross Negligence
(On Behalf Of The Nationwide Class)

158. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

159. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

160. Defendants owed a duty of care to Plaintiffs to manufacture, distribute, and sell the subject valsartan medications free from harmful defects and impurities.

161. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDEA.

162. Plaintiffs and Class Members were injured by ingesting an acutely toxic substance, to wit NDEA, which was negligently present in the valsartan medications manufactured, distributed, and sold by Defendants. Plaintiffs and Class Members also suffered economic damages from the purchase of the valsartan-containing medications.

163. Importantly, Plaintiffs and the Class Members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiffs and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

164. For the reasons set forth at length above, Defendants' conduct evinces a reckless disregard for the rights of others, and strongly suggests intentional wrongdoing.

165. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to

Plaintiffs and Class Members, and because Defendants failed to act promptly to remediate the harmful impurity, Defendants are grossly negligent and are liable to Plaintiffs and Class members for all injuries proximately caused by Defendants' gross negligence.

COUNT XII
Negligence
(On Behalf Of The Nationwide Class)

166. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

167. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

168. Defendants owed a duty of care to Plaintiffs to manufacture, distribute, and sell the subject valsartan medications free from harmful defects and impurities.

169. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDEA.

170. Plaintiffs and Class Members were injured by ingesting an acutely toxic substance, to wit NDMA, which was negligently present in the valsartan medications manufactured, distributed, and sold by Defendants.

171. Importantly, Plaintiffs and the Class Members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiffs and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

172. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to

Plaintiffs and class members, Defendants are negligent and are liable to Plaintiffs for all injuries proximately caused by Defendants' negligence.

COUNT XIII
Battery
(On Behalf Of The Nationwide Class)

173. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

174. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class, the New York Subclass, and the South Carolina Subclass against Defendants.

175. Defendants manufactured, distributed, and sold the contaminated valsartan medication to Plaintiffs and Class members with the knowledge and intent that Plaintiffs and Class members would ingest the medication. Defendants thus had knowledge that the harmful medication would come into contact the bodies of Plaintiffs and Class members.

176. The intended contact, *i.e.*, the medication being ingested by Plaintiffs, was harmful in nature because the medication contained the harmful impurity NDEA.

177. As such, Defendants committed an unlawful battery on Plaintiffs and Class members, who ingested the medication.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek judgment against Defendants, as follows:

A. For an order certifying the nationwide Class, the New York Subclass, and the South Carolina Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as representatives of the Class, Plaintiffs Duffy and Cacaccio as representatives of the New York Subclass, Plaintiff Byrd as representative of the South Carolina Subclass, and Plaintiffs' attorneys as Class Counsel to represent the Class, the New York Subclass, and the South Carolina Subclass members;

B. For an order declaring the Defendants' conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiffs, the nationwide Class, the New York Subclass, and the South Carolina Subclass on all counts asserted herein;

D. For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief;

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiffs and the Class, the New York Subclass, and the South Carolina Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of any and all issues in this action so triable of right.

Dated: December 14, 2020

Respectfully submitted,

BURSOR & FISHER, P.A.

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